Bacillus subtilis

Review Date: 01/02/2013
CAS #: Not applicable

Type	Fungicide, bacterial pathogen resistence.
Controls	Fungal and bacterial pests.
Mode of Action	Nutrient competition, site exclusion, induces plant's natural resistence to disease.

Thurston County Review Summary:

Bacillus subtilis is a bacterium that can be found in water, air, soil. and decomposing plants (Reference 1). As well as its use for pesticides, it is also fermented for the production of proteases, amylases, antibiotics, and specialty chemicals (Reference 2). There are currently four strains of Bacillus subtilis that are registered by the EPA for pesticidal use. These strains include; MBI 600 - used on crops or seeds, QST 713 - used on crops and in residential gardens, FZB24 and GB03 - used on turf, ornamentals, shrubs, nursery stock, crops and other agricultural sites).

Bacillus subtilis does not contain traits that cause disease and is not considered pathogenic to humans, animals, or plants (Reference 2), and is rated low in hazard by Thurston County's pesticide review criteria.

MOBILITY

Property	Value	Reference	Value Rating
Water Solubility (mg/L)	Value not applicable		
Soil Sorption (Kd=mL/g)	Value not applicable		
Organic Sorption (Koc=mL/g)	Value not applicable		

Mobility Summary:

Bacillus subtilis is a naturally occuring soil bacteria and the hazard for mobility is dependent on the potential for soil erosion at the application site. The hazard of pesticide mobility is rated low.

PERSISTENCE

Property	Value	Reference	Value Rating
Vapor Pressure (mm Hg)	Value not applicable		
Biotic or Aerobic Half-life (days)	Value not found		
Abiotic Half-life (days)	Value not found		
Terrestrial Field Test Half-life (days)	Value not found		
Hydrolysis Half-life (days)	Value not applicable		
Anaerobic Half-life (days)	Value not found		
Aquatic Field Test Half-life (days)	<2	1	Low

Persistence Summary:

Bacillus subtilis dies in water within 2 days, so, in aquatic environments the hazard of persistence is rated low. Bacillus subtilis is found most often in the spore stage that is very resistent to adverse environmental conditons but is biologically active in both aerobic and anaerobic conditions. Since it is a bacteria that can reproduce and is naturally found everywhere in soil, the hazard for persistence in soil is rated high.

BIOACCUMULATION

Property	Value	Reference	Value Rating
Bioaccumulation Factor	Value not found		
Bioconcentration Factor	Value not found		
Octanol/Water Partition Coefficient	Value not applicable		

Bioaccumulation Summary:

Bacillus subtilis is a living bacteria that has no known pathological effects in animals and is eliminated within 14 days of administration (Reference 1). Although bioaccumulation may not be the correct measure for Bacillus subtilis, accumulation from oral, inhalation, or dermal exposures is not likely to occur and cause toxic or pathogenic effects. The EPA concluded that Bacillus subtilis may inhabit the skin and/or gastrointestinal tract for a short period of time, but is unlikely to colonize other places in the human body (Reference 2). The hazard of bioaccumulation is rated low.

ACUTE WILDLIFE TOXICITY VALUES and Risk Assessment

Test Subject	Value	Reference	Value Rating
Mammalian (LD50)	>2,000 mg/kg bw	1	Low
Avian (LD50)	>5,000 mg/kg bw	1	Low
Honey bee or insect (LD50)	>24,000 ppm (diet)	1	Low
Annelida -worms (LC50)	Value not found		
Fish (LC50)	13.1 mg/L	1	Low - moderate
Crustacean (LC50)	>1.5 mg/Lfreshwater invertebrate	1	Low - moderate
Mollusk (LC50)	Value not found		
Amphibian (LD50 or LC50)	Value not found		

Acute Toxicity Testing and Ecotoxicity Summary:

In an acute toxicity test, rats were orally dosed with 113,000,000 colony forming units/animal without any adverse effects and it was eliminated from the animals within 14 days (Reference 1). Other toxicity testing with rats and birds indicate that it is low in toxicity to animials and birds. Testing with fish showed no toxicity at concentrations 10-times higher than concentrations that allowed for direct water application. Tests with honeybees and honeybee larvae indicate that Bacillus subtilis is non-toxic and non-pathogenic and the expected environmental concentration from pesticidal uses is 400 to 800 times less than the lethal dose to honeybees. Soil tests indicate that naturally occurring levels of this bacterium have been detected at 1,000,000 to 10,000,000 per gram of soil (Reference 2). Toxicity tests indicate that proposed pesticidal uses will have no adverse effects to earthworms.

The EPA reports that there have been 17 cases of bovine mastisis where Bacillus subtilis was thought to be the causal agent, although, it was not noted if the exposure to Bacillus subtilis was from soil or intoduced (Reference 2). The EPA believes that these mastitis cases are rare compared to other cases caused by other microorganisms. The hazard to non-target wildlife from exposures to Bacillus subtilis from pesticidal use is rated low.

ACUTE HUMAN TOXICITY - Risk Assessment

Subject and Scenario	Route	Dose of Concern	Exposure	Margin of Safety	Reference	Value Rating
Risk assessment criteria waived by EPA						
Risk assessment criteria waived by EPA						
Risk assessment criteria waived by EPA						
Risk assessment criteria waived by EPA						

Acute Toxicity Risk Assessment Summary:

Bacillus subtilis is known to produce the toxic chemical "subtilisin" that is capable of causing allergic reactions. This potential allergic response is only expected from high concentration exposures within fermentation facilities and exposure to it is regulated by the Occupational Safety and Health Administration. Risk to humans from potential exposures to Bacillus subtilis from pesticidal use is expected to be minimal due to its lack of acute oral toxicity/pathogenicity. (Reference 1).

Potential worst-case inhalation exposures to workers within a fermentation facility are calculated to range from 650 to 1,200 cfu/day (Reference 2). Rats were dosed up to 113,000,000 cfu/day without any adverse effects (Reference 1).

CHRONIC HUMAN TOXICITY HAZARDS

Property	Value	Adverse Effect	Reference	Rating
Carcinogenicity	Testing requirement waived by EPA			
Mutagenicity	Testing requirement waived by EPA			
Neurotoxicity - (NOAEL)	Value not found			
Endocrine Disruption	Value not found			
Developmental Toxicity (NOAEL)	Testing requirement waived by EPA			
Reproductive Toxicity (NOAEL)	Testing requirement waived by EPA			
Chronic Toxicity (NOAEL)	Testing requirement waived by EPA			

Chronic Toxicity Hazard Summary:

Due to lack of toxicity in acute toxicity testing, the EPA waived the requirements for carcinogenicity, immunotoxicity, reproductive fertility effects, and infectivity/pathogenicity testing (Reference 1). There have been cases in which Bacillus subtilis was attributed to human infections, although the infections only occurred in people with compromised immune systems (Reference 2). So, even in a fermentation facility, the potential for infection due to potential exposures to Bacillus subtilis is considered low by the EPA.

CHRONIC HUMAN TOXICITY - Risk Assessment

Subject and Scenario	Route	Dose of Concern	Exposure	Margin of Safety	Reference	Value Rating
Risk assessment criteria waived by EPA						
Risk assessment criteria waived by EPA						
Risk assessment criteria waived by EPA						
Risk assessment criteria waived by EPA						

Chronic Toxicity Risk Assessment Summary:

Occupational exposures to bacillus subtilis from pesticidal use is rated low in hazard due to the ubiquitous nature of these bacterium and because they have not produced toxicity in oral, dermal, or inhalation testing.

Metabolites and Degradation Products:

Bacillus subtilis is a living bacteria so an evaluation of degradation chemicals is not applicable.

Comments:

Bacillus subtilis is considered an eye irritant (EPA Toxicity Category II) and a skin irritant (EPA Toxicity Category II) but is not considered a skin sensitizer (Reference 1).

References

1. USEPA. Biopesticides and Pollution Prevention Division. Bacillus subtilis, Final Registration Review Decision. Case 6012. March 2010. Docket Number EPA-HQ-OPP-2007-1026.
2. USEPA. Biotechnology Program under the Toxic Substance Control Act (TSCA). Bacillus subtilis Final Risk Assessment, ATTACHMENT I--FINAL RISK ASSESSMENT OF BACILLUS SUBTILIS. (February 1997).